



## **Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States**

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# Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed (Last updated December 24, 2019; last reviewed December 24, 2019)

## Panel's Recommendations

- In the United States, the safest way to feed infants born to women with HIV is with formula, because breastfeeding presents an ongoing risk of HIV exposure after birth, and because suppressive maternal antiretroviral therapy significantly reduces, but does not eliminate, the risk of transmitting HIV through breastfeeding. Therefore, breastfeeding **is not recommended** for women living with HIV in the United States (AII).
- Women who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options (AIII).
- When women with HIV choose to breastfeed, they should be counseled to use harm-reduction measures to minimize the risk of HIV transmission to their infants (BIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

The standard recommendation for women living with HIV in the United States is to avoid breastfeeding, because:

- Maternal antiretroviral therapy (ART) reduces, but does not eliminate, the risk of HIV transmission via breast milk;
- Safe and affordable infant feeding alternatives are readily accessible in the United States;
- The postpartum period can be a challenging time to be fully adherent to ART; *and*
- There is a paucity of safety data on most modern ART regimens during breastfeeding.

The recommendations in the United States differ from those in many low-income and middle-income countries, where cost limits access to formula and where inadequate quantities of formula and/or unsafe water mixed into formula have been associated with high rates of infant mortality.<sup>1</sup> Women in some areas of the United States may also have limited access to safe water. Infant replacement feeding using formula (or formula powder mixed with safe water), banked breast milk, or a properly screened, HIV-negative wet nurse remains the only way to eliminate the risk of breast milk-associated HIV transmission. However, women may face environmental, social, familial, and personal pressures to consider breastfeeding, despite the risk of HIV transmission via breast milk.<sup>2-6</sup> A survey of 93 U.S. clinicians who provide specialty care to women with HIV revealed that one-third of the providers were aware that women in their care had breastfed their infants after being advised not to do so.<sup>7</sup>

A qualitative study of mothers with HIV in Canada found that many factors affected a woman's decision to breastfeed her infant; these included social, cultural, and emotional factors and concerns about HIV-related stigma.<sup>4</sup> Some women, especially those from a country or cultural background where breastfeeding is the norm, fear that not breastfeeding will lead to disclosure of their HIV status.<sup>2</sup> Multiple experts have called for a patient-centered, harm-reduction approach to counseling women with HIV on infant feeding options in high-income countries.<sup>2,8-11</sup>

This section of the guidelines is intended to provide tools to help providers counsel women with HIV on the potential risks of HIV transmission that are associated with breastfeeding and to provide a harm-reduction approach for women who choose to breastfeed despite intensive counseling. **It is not intended to be an endorsement of breastfeeding, nor to imply that breastfeeding is recommended for women with HIV in the United States.**

## Breastfeeding and Strategies to Reduce Risk of HIV Transmission

Both the evidence regarding the risks of HIV transmission via breastfeeding and the strategies to reduce this type of transmission come from studies conducted in low-income and middle-income countries, where rates of infant mortality are high and many families do not have access to safe water and affordable formula. Without maternal ART and infant antiretroviral (ARV) prophylaxis, the risk of a breastfeeding infant acquiring HIV from a mother with HIV is 15% to 20% over 2 years.<sup>12,13</sup>

Studies have shown that maternal ART throughout pregnancy and breastfeeding and infant ARV prophylaxis during breastfeeding can reduce, but not eliminate, the risk of breast milk-associated HIV transmission.<sup>14-18</sup> However, most of these studies only provided ARV drugs to women or their infants through 6 months postpartum and collected limited data on maternal plasma HIV viral load during breastfeeding.

As ART has become more widely available for women during pregnancy and the postpartum period, studies have evaluated HIV transmission during breastfeeding among women who initiated ART earlier in pregnancy and who continued ART longer than women in previous studies. **Among more than 500 mothers who were on ART in the Mma Bana study, two cases of HIV transmission via breastfeeding occurred. In these cases, maternal plasma and breast milk HIV RNA levels were <50 copies/mL at 1 month and 3 months postpartum.**<sup>19</sup> The PROMISE trial, which included more than 2,400 women with CD4 T lymphocyte cell counts  $\geq 350$  cells/mm<sup>3</sup>, compared the efficacy of prolonged infant prophylaxis to maternal ART in preventing HIV transmission during breastfeeding. Both treatments continued through cessation of breastfeeding or 18 months postpartum, whichever came first. This study reported estimated transmission rates of 0.3% at 6 months and 0.6% at 12 months in both arms.<sup>20</sup> Two cases of HIV transmission during breastfeeding were reported among 186 infants born during a study in Tanzania: the first occurred in the infant of a mother who had a high viral load 1 month after delivery, and the second occurred after a mother discontinued ART. There were no cases of HIV transmission among infants who were born to virally suppressed mothers who remained in care.<sup>21</sup>

Prior to the current accessibility of ART in low-income countries, studies demonstrated that exclusive breastfeeding during the first 6 months of life is associated with lower rates of HIV transmission than mixed feeding (a term used to describe infants fed breast milk plus other liquid or solid foods, including formula).<sup>22,23</sup> After 6 months, when complementary foods are required for adequate infant nutrition, demand for breast milk decreases and gradual weaning can occur. Rapid weaning over several days is not recommended, **because increased HIV shedding into breast milk and an increased rate of HIV transmission during rapid weaning were observed** in studies from low-income countries that were conducted before ART was widely accessible for breastfeeding women.<sup>24-26</sup> **There are currently not enough data to determine whether exclusive breastfeeding or mixed feeding has an impact on perinatal transmission in the context of effective ART.**

## Safety of Maternal and Infant Use of Antiretroviral Drugs During Breastfeeding

The non-nucleoside reverse transcriptase inhibitors (NNRTIs), nevirapine (NVP), efavirenz, and etravirine have been detected in breast milk; however, the levels of these drugs that have been detected in breast milk are lower than those seen in maternal plasma. Among protease inhibitors (PIs), lopinavir, nelfinavir, ritonavir, indinavir, atazanavir have been found in very low concentrations in breast milk, with little to no drug detectable in the blood of the breastfed infant.<sup>27</sup> Nucleoside reverse transcriptase inhibitors show more variability than PIs and NNRTIs. Tenofovir disoproxil fumarate (TDF) concentrations are very low in breast milk, and the drug is undetectable in the blood of the breastfed infant.<sup>27-29</sup> Emtricitabine and lamivudine (3TC) have more accumulation in breast milk and can sometimes be detected in the blood of the breastfed infant (in 19% and 36% of infants, respectively).<sup>27</sup> **Data on the transfer of integrase strand transfer inhibitors to breast milk in humans is limited; data do show that dolutegravir is found in breast milk at levels that are about 3% of those seen in maternal plasma.**<sup>30</sup> For more details on the passage of ARV drugs into breast milk, see the individual drug sections in [Appendix B](#).

One study showed a decrease in bone mineral content among breastfeeding mothers who were receiving TDF-based ART compared to mothers who received no ART, but whether this condition persists after discontinuation of breastfeeding is not known.<sup>31</sup>

In infants, serious adverse events that are associated with the use of ART by breastfeeding mothers appear to be relatively uncommon. In two studies that compared the efficacy of maternal ART (zidovudine [ZDV]-based ART in one study and TDF-based ART in the other) to infant NVP prophylaxis with no maternal ART during breastfeeding for prevention of postnatal HIV transmission, no significant differences in adverse events were observed between study arms.<sup>15,20</sup> One study reported that anemia occurred more frequently among infants who were exposed to ZDV-based ART during breastfeeding than among infants who were not exposed to ART.<sup>32</sup> An infant who acquires HIV while breastfeeding is at risk for developing ARV drug resistance due to subtherapeutic drug levels in breast milk.<sup>33,34</sup>

Likewise, the rates of serious adverse events among infants who receive extended ARV prophylaxis are low. In one study, the rate of adverse events in infants receiving 6 months of NVP was not significantly different from the rate in infants receiving placebo. A second study that compared two infant ARV prophylaxis regimens (lopinavir/ritonavir vs. 3TC) found no significant difference between the rates of adverse events among infants receiving the two regimens.<sup>15-17,20</sup> Studies to date have only examined short-term adverse events, and there is little data on whether there might be long-term consequences of these drug exposures.

## Approach to Counseling and Management

Formula, banked donor milk, and milk from an HIV-negative wet nurse who has been properly screened remain the only completely reliable methods of preventing HIV transmission during breastfeeding. The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) recommends that women living with HIV in the United States not breastfeed their infants. However, patient-centered counseling on infant feeding must balance maternal psychosocial concerns, the health benefits of breastfeeding for the infant, and the risks of HIV transmission. Similarly, **the British HIV guidelines recommend using formula as the safest approach to infant feeding, but they suggest supporting women who opt to breastfeed.**<sup>11</sup> Providers can initiate counseling with a nonjudgmental inquiry about infant feeding early in pregnancy, and then engage the mother by offering joint problem solving and shared decision making. One approach is to say, “In the United States, we recommend formula feeding to avoid the risk of HIV transmission to your baby through breast milk. Do you have any questions or concerns about this?” For women who are considering breastfeeding, the Panel recommends engaging each woman privately in a nonjudgmental conversation about the motivation behind her desire to breastfeed, as well as consulting with the clinician(s) who will be managing the infant’s care.

If, despite extensive counseling, a woman decides to breastfeed, harm-reduction measures should be taken to reduce the risk of HIV transmission. **Ideally, the woman should be adherent to her ARV regimen, she should maintain a suppressed viral load during pregnancy (or at least during the third trimester of pregnancy), and she should be fully engaged in her own care.** Harm-reduction measures may include:

- Supporting maternal ART adherence and engagement in care both during pregnancy and throughout breastfeeding.
- Documenting consistent viral suppression prior to delivery and throughout breastfeeding. This can be accomplished by monitoring maternal plasma viral loads every 1 to 2 months during breastfeeding. Plasma viral loads should also be monitored whenever nonadherence to ART is suspected. If maternal viral load becomes detectable, consult an expert immediately **and consider weaning the infant.**
- Breastfeeding exclusively for up to 6 months postpartum, followed by breastfeeding in combination with the introduction of complementary foods. **However, this recommendation is based on studies of exclusive breastfeeding and nonexclusive breastfeeding that were completed before effective ART was widely available.**

- Developing a plan for weaning with input from the family and providers. Rapid weaning over a few days **is not recommended**, but data on weaning are lacking for infants born to women who are receiving ART and who are virologically suppressed.
- **Administering at least 6 weeks of ARV prophylaxis with ZDV and/or NVP to infants.** In non-breastfeeding infants, there is high-quality evidence that 4 to 6 weeks of infant prophylaxis with ZDV prevents HIV transmission (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)). The most extensively studied prophylaxis in breastfeeding infants is daily NVP, which has been shown to be safe and effective when used for extended prophylaxis in infants whose mothers are **not** receiving ART.<sup>16,20</sup> If the mother is receiving ART, infant ARV prophylaxis can be discontinued after 6 weeks. Among mothers who were enrolled in the HPTN 046 trial and who received suppressive ART, there was no difference between the rates of postnatal transmission for infants who received NVP and infants who received placebo.<sup>16</sup> **There are no data to support the added benefit of giving ARV drugs for more than 4 weeks to 6 weeks to infants of mothers who are on suppressive ART.** However, some experts have felt more comfortable continuing infant ARV prophylaxis for **1 week to 4 weeks** after cessation of weaning, even when the mother is receiving suppressive ART.<sup>35</sup>
- Monitoring the infant for HIV acquisition during breastfeeding. A reasonable approach to infant monitoring would include virologic HIV testing at the standard time points (see [Maternal HIV Testing and Identification of Perinatal HIV Exposure](#)) and then every 3 months throughout breastfeeding, followed by monitoring at 4 to 6 weeks, 3 months, and 6 months after cessation of breastfeeding.
- Promptly initiating a full ART regimen for the infant in the unlikely event of HIV transmission via breastfeeding. Resistance testing should be done on the infant viral isolate. If resistance is identified, the treatment regimen can be adjusted appropriately.
- Promptly identifying and treating maternal mastitis and infant thrush. Both conditions increase the risk of HIV transmission through breastfeeding.<sup>36-38</sup> Milk from the affected breast should be pumped and discarded until mastitis resolves.

The immediate postpartum period poses unique challenges to adherence to medical care and ART. **Although it has been shown that people with undetectable viral loads cannot transmit HIV through sexual contact, there are currently not enough data to say the same for transmission during breastfeeding. Many questions remain as to the mechanism for breast milk-associated HIV transmission in the cases where it has occurred. HIV RNA in cell-free breast milk may be controlled with ART, but cell-associated HIV (usually measured by HIV DNA) may provide a latent reservoir of HIV that is capable of causing perinatal infection via breastfeeding even among women on ART.**<sup>39-41</sup> Close follow-up and enhanced support services should be considered for women who are planning to breastfeed (see [Postpartum Follow-Up of Women Living with HIV Infection](#)).

Clinicians who are caring for a woman with HIV who is considering breastfeeding should consult with an expert and, if necessary, the Perinatal HIV Hotline (888-448-8765).

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